FDA 510(k) Premarket Notification

CLEARED

K223059 Xenco Medical InterAlign Cervical Interbody System

Jun 7, 2023
250 days to decision

K223059 · Product code: **OVE** · Orthopedic
Source: https://www.510kdatabase.net/k223059/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Sep 30, 2022
Decision date	Jun 7, 2023
Days to decision	250 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Xenco Medical, LLC**
Location	San Diego, CA, US
Contact	Jason Haider
510(k) history	16 submissions · 16 cleared · 2014-2025

REGULATORY CONSULTANT

Consulting firm	**Secure BioMed Evaluations**
Contact	Linda Braddon

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov